QAM 12080: Self-Assessments

Revision History

Author	Description of Change	Revision No. & Date
Kathy Zappia / Jemila Adetunji	Summary of changes to the procedure: - Additional verbiage some of the terms within the acronyms & definitions section – to enhance robustness - Statements of clarification added to the responsibilities section (no change in responsibilities) - Update of title – ESH&Q Section Head to Assistant Director for ESH&Q - Rewording within a few other areas of the document for clarification but no changes	July 2014
Kathy Zappia	Initial release of QAM chapter 12080. This replaces the original Self-Assessments Procedure 3902.1003 rev. 001.3 published by the former OQBP, and cancels the OQBP Procedure upon publication.	December 2013

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1.0 INTRODUCTION

This procedure provides the instructions for the performance of Fermilab self-assessments by organizations internal to Fermilab. Laboratory Management including the Directorate, Division/ Section Heads, Management System Owners, and Project Managers are expected to plan and conduct regularly scheduled self-assessments that review their organizations/projects to identify and correct problems that would hinder the achievement of their mission, objectives, and performance requirements. It is expected that the selection of self-assessment topics will be guided by the evaluation of risks using a graded approach, and conducted in accordance with applicable requirements and regulations.

2.0 SCOPE

The scope of this procedure encompasses self-assessments conducted at Fermilab but with the exception of ES&H self-assessments. ES&H self-assessments ensure the Fermilab ES&H Program is implemented properly, and is explained in detail in FESHM chapter 1010.1, ES&H Self-Assessment Program.

3.0 ACRONYMS & DEFINITIONS

- CAP - Corrective Action Plan
- QAR - Quality Assurance Representative
- Assessment - A review, evaluation, surveillance, or audit where a systematic approach is used to evaluate processes, systems or services to determine compliance to specified requirements and effectiveness; with the goal of identifying best practices and/or areas of non-compliance. An assessment usually results in corrective actions where appropriate resolution is required.
- Independent Assessment – Assessments conducted on an aspect of Fermilab operations by the ESH&Q Section Quality Assurance Group or an outside organization.
- Management Assessments - Self-Assessments conducted by the Directorate, D/S Heads, or Fermilab Management System Owners to assess the performance of their organizations and to identify and correct problems that will hinder the organization from achieving their mission, objectives, and performance requirements.
- Project Management Assessments – Self-Assessments conducted by Project Managers to evaluate the project's products and services to determine whether the project's objectives and key performance parameters (KPP's) are being achieved.

- Risk-Based Planning - Risk-based planning focuses on the strategic, regulatory, financial, and business risks to which the laboratory has exposure. The goal is to customize a dynamic, defensible assessment plan that addresses the unique needs and risks of the work that is being performed.

- Self-Assessment - An assessment on one's own responsibilities, processes, organization, etc. to determine and document whether specific requirements have been met, and what improvement opportunities are present.

4.0 RESPONSIBLILITIES

4.1 Divisions/Sections Heads, Management System Owners & Project Managers

- Ensure compliance with this procedure for their areas including flow down of requirements and awareness
- Document and schedule self-assessments based on risk using a graded approach
- Provide the necessary resources to implement this procedure and complete self-assessments
- Ensure any non-conformances found during self-assessments are entered into iTrack, tracked to completion, and properly closed.
- Ensure that corrective actions are implemented, entered into iTrack, tracked to completion, and properly closed.
- Ensure that the D/S/P QAR is informed of self-assessments initiated using this procedure
- Ensure that the self-assessment activities and results are entered into the iTrack database; including all findings, non-conformances, opportunities for improvement, best practices, and recommendations

4.2 Assistant Director for ESH&Q

- Provide support to management within the scope of this procedure
- Review periodic trending and analyses of self-assessment items to verify that root causes are being adequately identified and to determine if items are appropriately and effectively addressed
- Ensure that the effectiveness reviews of corrective actions are conducted
- Assume responsibility for the content and maintenance of this procedure

4.3 Assessors

- Ensure compliance with this procedure
- Plan, organize, and conduct self-assessments in alignment with organizational leadership self-assessment objectives
- Report the results of self-assessments to management system owners, stakeholders and respective QARs

4.4 QARs

- Review self-assessment results and reports results to the QA Subcommittee
- Provide support to assessment leaders and organization as necessary
- Verify that corrective actions are documented, tracked and implemented when requested

5.0 PROCEDURES

5.1 Scheduling

Self-assessment schedules are determined by management (D/S/P's or Management System Owners), and are based on requirements and risks using a graded approach. Scheduling a self-assessment should be determined by using a risk-based planning approach, and should include the following inputs:

- Program Execution Plans
- Reorganization of D/S/P
- Other assessments that have highlighted a particular problem, area of concern or elevated risk
- Recurring incidents or non-conformances
- Policy, process, or procedure changes
- Requirement changes (i.e. DOE Order updates, Project scope changes)
- Events or incidents
- Assurance Council or senior management requests

Self-assessment schedules must be updated on a yearly basis. The schedule shall be posted and communicated so that the organization is aware of the schedule for the upcoming year, and it shall be communicated to the organization's QAR. The QAR shall then communicate the self-assessment schedule to the QA Subcommittee.

Schedules are meant to be working documents, and should be revised as changes occur. If a self-assessment is postponed or canceled a rationale should be provided in the schedule.

5.2 Planning

Those employees selected to be assessors are responsible for planning the self-assessment.

5.2.1 If desired, complete the Assessment Plan Template. The template includes the following:

- Organization assessed – this should include their organization's name, and/or any specific processes that are to be assessed.
- Purpose & Scope of Assessment – This is the rationale for the assessment, why the assessment is needed (e.g. requirement, DOE order, previous nonconformity, lessons learned, etc.).
- Assessment Schedule – the tentative schedule that has been agreed upon with the participants of the assessment.

- Criteria & Requirements to be assessed – this section should list the specific requirements or criteria that are to be assessed.

5.2.2 Distribute the Assessment Plan to all participants of the assessment to ensure their agreement and awareness.

5.3 Execute Self-Assessment

The assessor(s) from the organization shall direct the activities of the assessment and also serve as the direct point of contact with the assessed organization's management and all participating staff members.

5.3.1 Conduct the Assessment Interviews and Inspections

The assessment is conducted in accordance with the assessment plan and schedule. Assessors obtain the documentation and evidence necessary to verify compliance to the requirements outlined in the Assessment Plan. Activities performed during the assessment can include (but are not limited to):

- Scheduling and conducting interviews
- Reviewing and examining documents and records
- Inspection of facilities or observing work activities

5.3.2 Document Findings

Assessors should log any documents or records reviewed, list all personnel interviewed, and document any findings, nonconformities, continual improvement opportunities, or best practices found during the assessment.

All findings, nonconformities, continual improvement opportunities, and best practices found during the assessment should be agreed upon by the participants of the assessment and management before they are officially documented in iTrack.

5.4 Enter Findings in iTrack

All findings, nonconformities, continual improvement opportunities, recommendations, and best practices documented during the assessment that require actions or response to be taken shall be entered into iTrack by the assessor (or designated iTrack user) and assigned an owner. (See the iTrack webpage for more information on iTrack including the iTrack User Guide). The owner of the issue is responsible for delegating corrective actions and other activities necessary to close out the issue in iTrack in accordance with Fermilab's Corrective & Preventive Action Procedure (see QAM 12040).

5.5 Reporting

The assessor shall complete a Self-Assessment Report Template once the audit has concluded and all of the issues have been agreed upon by all parties. The Self-Assessment Report includes the following information:

- Date(s) of assessment – actual dates of the assessment

- Organization assessed – organization name
- List of participants – who was assessed
- List of assessors – who were the assessors
- Scope – what processes were reviewed, what work sites were inspected, etc…
- Criteria/Requirements – what criteria and requirements were used as input to the self-assessment
- Interviews – short synapsis of any interviews that took place, this may be not applicable (N/A) if the self-assessment was inspection based
- List of documents reviewed
- Report – summary of what took place during the self-assessment and the results
- Opportunities for Improvement
- Best Practices Observed – list any best practices seen during the self-assessment
- Lessons Learned – identify any lessons learned reviewed during the self-assessment, but also any identified as a result of the self-assessment
- Findings / Nonconformities – details of the actual nonconformities found

5.6 Distribution

The Self-Assessment Report shall be distributed to all of the assessment participants, management of the organization, the QAR, and others as determined by the D/S/P or Management System owner. The QAR shall share the results with the QA Subcommittee so that lessons learned, issues found, and other best practices can be shared with other organizations.

5.7 Records

All records that were generated by the assessment, including the Assessment Plan, Self-Assessment Report, checklists created, other planning documents, etc… shall be kept in a location accessible by the assessed organization. Accessible locations can be (but not limited to) SharePoint or DocDB.

5.8 Effectiveness Reviews of CAPs

The ESH&Q Section will periodically follow-up with assessed organizations through the designated QAR to ensure CAPs are being addressed and implemented.

5.8.1 On a periodic basis, the Quality Assurance group of the ESH&Q Section shall review the effectiveness of the actions taken to resolve and prevent the issue from recurring at the conclusion of implementing a corrective action plan. Review of the corrective action plan can include the following actions (but are not limited to):

- Review of the evidence of the implemented actions
- Follow-up interviews with parties involved in the implementation of the corrective actions
- Follow-up interviews with parties impacted by the implementation of the corrective actions

5.8.2 Disposition of the initial corrective action plan is determined based on the review, and can result in one of the following outcomes:

5.8.2.1 Corrective action plan implementation was effective. If this is the determination no further actions are necessary.

5.8.2.2 Corrective action plan implementation was not effective. If it is determined the actions taken to resolve the issue and prevent recurrence are ineffective, then the original owner of the nonconformity shall be contacted, and a new plan requested.

6.0 REFERENCES

Assessment Plan Template: http://esh-docdb.fnal.gov/cgi-bin/RetrieveFile?docid=2632

Self-Assessment Report Template: http://esh-docdb.fnal.gov/cgi-bin/RetrieveFile?docid=2633

FESHM: http://esh.fnal.gov/xms/FESHM

iTrack: http://esh.fnal.gov/xms/General/frESHTRK